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MS APPEAL BRIEF - PATENTS
PATENT
0933-0162P

IN THE U.S. PATENT AND TRADEMARK OFFICE

In re application of		Before the Board of Appeals	
Eino E. HAKALEHTO		Appeal No.:	
Appl. No.:	09/646,043 ✓	Group:	1645
Filed:	October 25, 2000	Examiner:	K.SHAHNAN-SHAH
Conf.:	3800		
For:	METHOD FOR DETECTING MICROBES FROM AN ENRICHMENT CULTURE		

APPEAL BRIEF TRANSMITTAL FORM

MS APPEAL BRIEF - PATENTS
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

September 13, 2004

Sir:

Transmitted herewith is an Appeal Brief on behalf of the Appellants in connection with the above-identified application.

☐ The enclosed document is being transmitted via the Certificate of Mailing provisions of 37 C.F.R. § 1.8.

A Notice of Appeal was filed on July 13, 2004.

☒ Applicant claims small entity status in accordance with 37 C.F.R. § 1.27

The fee has been calculated as shown below:

☐ Extension of time fee pursuant to 37 C.F.R. §§ 1.17 and 1.136(a) - $0.00.

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Respectfully submitted,

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Attachment(s)

(Rev. 02/08/2004)

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APPEAL BRIEF UNDER 37 CFR §41.37

Appellant submits the following Appeal Brief in connection with the Notice of Appeal filed on July 13, 2004 in connection with the above-identified application.

(i) Real Party in Interest

The real party in interest is Appellant Elias Eino Hakalehto, an independent inventor. This application has not been assigned.

(ii) Related Appeals and Interferences

There are no related appeals or interferences associated with this application.

(iii) Status of Claims

Claims 14-17, 19, 20, 22 and 23 are currently pending and finally rejected. Claims 1-13, 18, 21 and 24-26 have been canceled. The rejection of claims 14-17, 19, 20, 22 and 23 is being appealed herein.

(iv) Status of Amendments

All amendments to the claims have been entered as of the Final Office Action dated January 15, 2004. There are no outstanding amendments.

(v) Summary of Claimed Subject Matter

The present invention as recited in the broadest claim, claim 14, is directed to a method for detecting enteric bacteria having fimbriae, comprising detecting said bacteria from a cultivation medium within the time period of 3 to 10 hours from the onset of cultivation, by detecting fimbrial antigens which are expressed into the medium before an actual logarithmic growth phase of the bacteria or in the beginning of the logarithmic growth phase. These features of the invention are also described in the specification at page 4, lines 10-30.

(vi) Grounds of Rejection to be Reviewed on Appeal

Claims 14-17, 19, 20, 22 and 23 stand rejected under 35 USC §103(a) over U.S. Patent 5,510,241 to Thorns et al. (hereinafter

Thorns '241) in view of the journal article Blackburn et al. (1993)(hereinafter "Blackburn").

(vii) Argument

The Claims on Appeal stand or fall together.

I. Rejection under 35 USC 103(a) over Thorns '241 in view of Blackburn

The Examiner has failed to establish a *prima facie* case of obviousness by failing to show that the cited references when combined teach or suggest all the limitations of the present invention of claims 14-17, 19, 20, 22 and 23. The Examiner also failed to establish that one of ordinary skill in the art would be motivated to combine the cited references to arrive at the present invention.

According to *In re Fine*, 5 USPQ2d 1596,1598 (Fed. Cir. 1988), a *prima facie* case of obviousness is established when the Examiner establishes that there is some evidence of an objective teaching in the cited art or in the general knowledge within the field of art that would motivate one to combine the relevant teaches in the cited references. The combination of teachings must disclose or suggest each and every element of the claimed invention. The Examiner has failed to establish such evidence in this case.

The Examiner attempts to establish a *prima facie* case of obviousness in the Final Office Action dated January 15, 2004 at

page 4. The Examiner states that it would be *prima facie* obvious to one having ordinary skill in the art at the time the invention was made to combine the rapid method of screening taught by Blackburn and the method taught by Thorns '241 to obtain the present invention. The Examiner seems to state that the motivation for making the combination is that rapid screening methods for bacteria, such as Salmonella are needed. No evidence to support the Examiner's statement has been provided. The Examiner also states that one would be motivated to develop a better method with a shortened cultivation period for detecting bacteria that are major causes of food-born illnesses. Again, no evidence of such motivation is provided.

The Examiner relies on the teachings of Thorns '241 for allegedly disclosing a method for detecting the presence of Salmonella species expressing fimbrial antigens, which have been grown on a select medium. The Examiner points to column 7, Example 1. The Examiner admits that Thorns '241 fails to teach a rapid method of detection where the detection assay is effective within 3 to 10 hours from the onset of cultivation. Therefore, the Examiner relies on Blackburn for allegedly teaching the reduction of the incubation periods for rapid methods of detection in the art of microbiology. The Examiner points to page 199 of Blackburn.

Appellant submits that the combination of Thorns '241 and Blackburn fail to disclose or suggest all the elements of the

present invention. Appellant also submits that neither Thorns '241 nor Blackburn suggest modifying the method that is taught in Thorns '241 with the teachings in Blackburn. Blackburn merely suggests shortening the selective enrichment steps. Blackburn states in the last sentence of the article that "the application of separation and concentration techniques, together with different approaches to pre-enrichment to prevent competitive inhibition of salmonella, should improve the reliability of salmonella testing and reduce the length of cultural enrichment." This passage establishes that Blackburn is not concerned with shortening the detection time from the time of onset of cultivation in a one step cultivation detection assay.

In the Introduction (page 199), Blackburn discloses general detection methods involving sequential cultural steps include the following four steps: pre-enrichment (16-20 h), selective enrichment (18 - 48 h), plating on selective media (24-48 h) and biochemical and serological comfirmation (4-48 h). Then in point 2.1 on page 199 ("Shortened liquid enrichment"), Blackburn discloses that attempts have been made to reduce the incubation periods of either pre-enrichment or selective enrichment to 6-8 h. It is clear that Blackburn is referring to the four-step-method, wherein the time period of one of the first two steps is reduced. This teaching is inconsistent with the present invention, since the present invention has a one step

cultivation step. Moreover, in the present invention, it is the one step cultivation step that is shortened.

Blackburn does appear to address the one step method at page 205, left column, 2nd paragraph. However, the shortest cultivation period disclosed for these putative one-step-methods seems to be 13 hours. This disclosure still does not motivate one of ordinary skill because the cultivation period of a one-step-method is not shortened or suggested to be shortened.

Finally, Blackburn states at point 8 on page 208, right column, last paragraph that, "At present, all these rapid and alternative techniques are dependent on some form of cultural enrichment to obtain a sufficient cell concentration for detection." This is not the case in the present invention.

Appellant submits that the teachings in Blackburn would not motivate a skilled artisan to reduce the time period of only one cultivation step in Thorns '241 because a sufficient number of the micro-organisms cannot be obtained with such a short cultivation step. Moreover, the teaching of shortening of one of the four cultivation steps cannot hardly be a motivation to shorten a time period of a one-step-method as in Thorns '241 and the present invention.

Appellant also submits that Thorns '241 discloses a method for detecting the presence of *Salmonella* species expressing fimbrial antigens, which have been grown on a selected medium.

Please note that Thorns '241 fails to teach the time period of 3 to 10 hours from the onset of cultivation.

In contrast, Thorns '241 explicitly teaches that the "Growth of the Salmonella micro-organisms on the medium in the process of the invention may be under entirely standard conditions, e.g. by incubation at about 37 °C until a sufficient number of the micro-organisms having epitopic sites on their fimbriae have grown, for example typically by overnight incubation." (See column 5, lines 43-48.) (Emphasis added.) The incubation period is further described in the examples at column 14, lines 13-14, which state that "Strains were cultivated in liquid or solid medium for 18 hours at 37 °C." (Emphasis added.) Please also note that in all the examples, the bacterial cultivations were inoculated from previously isolated cultures. Consequently, the time period for *Salmonella* detection from food samples when using the method disclosed in Thorns '241 is expected to be even longer than the 18 or so hours disclosed.

As such, it is clear that the method of Thorns '241 is based on growing "a sufficient number of the micro-organisms" during a cultivation step of at least 18 hours. Thus a skilled artisan would have understood that the method of Thorns '241 is relying upon cell multiplication of enteric bacteria and is not equivalent to the method of the present invention, namely detecting said bacteria during the lag phase or right after the

lag phase, wherein fimbriae antigens are surprisingly strongly expressed. The present invention is not merely directed to a fast detection method, but a fast detection method where fimbriae antigens are measured during a specified period.

Clearly, the combination of Thorns '241 and Blackburn fails to disclose or suggest all the elements of the present invention. Although Thorns '241 discloses some of the assay steps, Thorns '241 fails to disclose the actual detection step after the requisite shortened cultivation period of 3 to 10 hours. Moreover, Blackburn fails to suggest a one step cultivation step where the cultivation period is 3 to 10 hours. As such, the combination of references is deficient.

Appellant submits that even if all the elements were present between the two references, there is no motivation to combine Thorns '241 and Blackburn. The combination, if made, would clearly teach one of ordinary skill in the art that when detecting Salmonella bacteria, he/she should rely upon cell multiplication, which takes at least 18 hours according to Thorns '241 and at least 13 hours according to Blackburn. This is not the case in the present invention.

At best, the Examiner has pointed out a combination of references that make it "obvious to try" to attain the claimed invention. "Obvious to try" is not the standard under which to reject claims under 35 USC 103. See *In re Dow Chemical Co.*, 5

USPQ2d 1521, 1532 (Fed. Cir. 1988) (rejecting the obviousness to try standard).

If one were to try to combine the references to obtain the present invention, it would be an impermissible hindsight reconstruction. Also, the combination suggests longer periods of cultivation than as recited in the present invention. These longer periods of cultivation would cause diminishing of fimbriae antigen signals regardless of the cellular growth and thus deteriorate the results of the measurement. As such, Appellant submits that the method would be inoperative. The previous state of the art teaches long cultivation steps so that one is able to obtain good cell multiplication before the actual detection step.

For the foregoing reasons, Appellant submits that the obviousness rejection should be reversed as no *prima facie* case of obviousness has been established.

The small entity Appeal Brief filing fee is attached hereto.

If necessary, the Commissioner is hereby authorized in this, concurrent, and future replies, to charge payment or credit any overpayment to Deposit Account No. 02-2448 for any additional fees required under 37 C.F.R. § 1.16 or under 37 C.F.R. § 1.17; particularly, extension of time fees.

Respectfully submitted,

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Attachments: Appendices (viii-x)

(viii) Claims Appendix

Claims 1-13. (Canceled)

Claim 14. (Previously Presented) A method for detecting enteric bacteria having fimbriae, comprising detecting said bacteria from a cultivation medium within the time period of 3 to 10 hours from the onset of cultivation, by detecting fimbrial antigens which are expressed into the medium before an actual logarithmic growth phase of the bacteria or in the beginning of the logarithmic growth phase.

Claim 15. (Previously Presented) The method according to claim 14, wherein the fimbrial antigens are detected immunologically using antibodies.

Claim 16. (Previously Presented) The method according to claim 15, wherein the fimbrial antigens are detected in 3 to 4.5 hours after the onset of the cultivation.

Claim 17. (Previously Presented) The method according to claim 14, wherein the detected fimbrial antigens are proteins.

Clam 18. (Canceled)

Claim 19. (Previously Presented) The method according to claim 14, wherein the fimbrial antigens are type 1 fimbriae proteins.

Claim 20. (Previously Presented) The method according to claim 14, wherein the fimbrial antigens are detected with antibodies, which have been produced against the synthetic peptide sequence Ala Ser Phe Thr Ala Ile Gly Asp Thr Thr Ala Gln Val Pro Phe Ser Ile Val SEQ ID NO: 1.

Claim 21. (Canceled)

Claim 22. (Previously Presented) The method according to claim 14, wherein the detected bacteria are pathogenic enteric bacteria.

Claim 23. (Previously Presented) The method according to claim 22, wherein the detected bacteria belong to the genus *Salmonella*.

Claims 24-26. (Canceled)

ix. Evidence Appendix

(Not applicable.)

x. Related Proceedings Appendix

(Not applicable.)